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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,477	04/20/2004	Swee Hin Teoh	NUS-8 DIV I	4933
7590 Mark J. Pandiscio Pandiscio & Pandiscio 470 Totten Pond Road Waltham, MA 02154	07/10/2008		EXAMINER WOODWARD, CHERIE MICHELLE	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 07/10/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,477	TEOH ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 May 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 40,43,44,48,50,51 and 56-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 40,43,44,48,50,51 and 56-64 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/22/2008</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Formal Matters

1. Applicant's Response, filed 22 May 2008, is acknowledged and entered. Claims 1-39, 41, 42, 45-47, 49, and 52-55 have been cancelled by Applicant. New claims 57-64 have been added. Claims 40, 43, 44, 48, and 50-51, and 56-64 are pending and under examination.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 22 May 2008 has been considered by the Examiner. A signed copy is attached hereto.

Response to Arguments

Objections/Rejections Withdrawn

3. Objections/Rejections over claims 52-55 are withdrawn as moot in light of Applicant's cancellation of these claims.
4. The rejection of claims 40, 43, 44, 45, 48, 50, and 51 under 35 U.S.C. 112, second paragraph, because of the trademarked company name "STRATASYS, INC" and the trade name "FDM 3D MODELER" in claims 40 and 48, is withdrawn in light of Applicant's amendments.
5. The rejection of claims 40, 43, 44, 48, 50, 51, and 56 under 35 U.S.C. 102(b) as being anticipated by Cima et al., US Patent 5,518,680 (21 May 1996, benefit to 23 February 1994) is withdrawn in light of Applicant's clarification of the criticality of the lay-down pattern and the cancellation of claims 52-55, which cast doubt on this criticality. However, the claims remain rejected under this same reference under 35 USC 103(a) for the reasons of record and the reasons set forth below.
6. The rejection of claims 40, 43, 44, 48, 50, 51, and 56 under 35 U.S.C. 103(a) as being unpatentable over Richter et al., US Patent 6,280,478 (28 August 2001), benefit to 4 January 1999) and Cima et al., US Patent 5,518,680 (21 May 1996, benefit to 23 February 1994), is withdrawn as moot in light of the new rejection set forth below.

Claim Rejections Maintained***Claim Rejections - 35 USC § 112, First Paragraph******Written Description***

7. Claims 40, 43, 44, 48, 40, 51, and 56 remain rejected and new claims 57-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record and the reasons set forth below.

Applicant argues that one of ordinary skill in the art would reasonably conclude that Applicant's disclosure adequately describes the claimed invention because the features of the apparatus of claims 40 and 48 are taught by the present application (Remarks, p. 8, last paragraph). Applicant argues that the apparatus is described in Example 1 and in the figures (Remarks, p. 8, last paragraph). Applicant argues that the apparatus of claims 40 and 48 could be used in tissue engineering having a lay-down pattern forming triangular and five-sided polygonal pores (Remarks, p. 9, first paragraph). Applicant also argues that MPEP 2163 and MPEP 2163(II)(3)(a)(ii) provides that written description for a genus may be satisfied through sufficient description of a representative number of species by disclosure of relevant identifying characteristics (Remarks, p. 8, third paragraph and p. 9, second paragraph). Applicant's arguments have been fully considered, but they are not persuasive.

There is a single species of the claimed genus disclosed that is within the scope of the claimed genus, *i.e.* a scaffold fabricated using PCL and PCL/HA filaments with a FDM rapid prototyping system with triangular and polygonal pores, with a specific offset yield strength, specific lay-down pattern of angles, specific scaffold dimensions, specific porosity, produced with a specific sized extruder tip, generated at a specific temperature, and with specific requirements for compression (see Example 1, p. 48-54 of the disclosure). The disclosure of a single species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described.

Regarding Applicant's argument that the specification provides a species that is representative of the claimed genus of apparatuses, Applicant has not sufficiently described enough of the physical characteristics of the claimed genus of apparatuses such that they can all sufficiently be described by the exemplary embodiment in the specification (*i.e.* at Example 1). The claimed apparatus comprises any scaffold structure comprising at least three-dimensional horizontal layers and vertical walls of melt extrusion filament comprising at least one of PCL and PCL/HA where the lay-down patterns form horizontally disposed triangular pores (claim 40) or five-sided polygon pores (claim 48). A broad range of pore sizes is encompassed in claims 50 and 51 (comprising 200-700 μ m) and newly added claim 60 and

63 recite that the vertical walls are 260-360 μm in diameter (within the range of the 260-370 μm in diameter disclosed on page 40, lines 14-15, of the specification). However, no specific offset yield strength, overall scaffold dimensions, porosity density, extruder tip size (which makes the dimensions of the filaments variable), compression requirements, or limitations on other components that may be included in the scaffold apparatus are set forth in the claims such that they would otherwise limit the genera of multiple apparatuses encompassed by the claims. The limitations of Example 1 of the specification are not fully set forth in the instant claims. While “examples explicitly covering the full scope of the claim language” typically will not be required, **a sufficient number of representative species must be included** to “demonstrate that the patentee possessed the full scope of the [claimed] invention.” Lizardtech v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005).

Newly added claims 57-64 recite specific angular degrees of the lay-down pattern, but the composition of the claimed genus of apparatuses is not adequately defined. For example, claims 40 and 48 recite the phrase "comprising." The only composition limitations for the claimed genus of apparatuses is that the comprise "at least one of PCL and PCL/HA." The broadly claimed genus of apparatuses may comprise components or substances which are not adequately described in the specification or the art and which extend beyond the limitations of the disclosure of the species exemplified in Example 1. Applicant has not adequately described the structural features of the apparatuses of the claimed genera to demonstrate that Applicant was in possession of the genus at the time the application was filed.

Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features (see, Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1895 (Fed. Cir. 2004); accord Ex Parte Kubin, 2007-0819, BPAI 31 May 2007, opinion at p. 16, paragraph 1). In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus, which is a three dimensional apparatus for use in tissue engineering having interconnectivity between channels throughout the scaffold structure where the walls are laid-down in patterns forming horizontally disposed triangles or five-polygons or different lay-down patterns. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 40, 43, 44, 48, 50, 51, and 56-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al., US Patent 6,280,478 (28 August 2001), benefit to 4 January 1999), Cima et al., US Patent 5,518,680 (21 May 1996, benefit to 23 February 1994), and Jang et al., US Patent 6,129,872 (10 October 2000, benefit to 29 August 1998), as evidenced by Kuslich, US Patent 5,549,679 (27 August 1996).

The Examiner finds the following facts:

- a. The claims are drawn to an apparatus for use in tissue engineering comprising a scaffold structure.

- b. The '478 patent teaches a customized three-dimensional, layered, scaffold structure for use in tissue engineering for an individual patient including the aspect of intercrossing filaments stacked in horizontal planes (see abstract; Figures 1 and 2; Examples 1 and 2, columns 3 and 4) (compare instant claims 40 and 48). The extrusion of the extrudable mixture and the formation of the lattice structure can be effected using known apparatus such as known apparatus for injection molding of particulate materials, known apparatus for solid free form manufacture by means of fused deposition molding of ceramics, known apparatus for three-dimensional printing of ceramics, known apparatus for multiphase jet solidification of ceramics, and/or known apparatus for stereolithography (column 2, lines 9-16) (compare instant claims 40 and 48). Fused deposition modeling is taught at column 3, line 66 (compare claims 40 and 48). Extrusion compositions comprising hydroxyapatite and polymers or elastomers are taught at column 2, lines 17-29 (compare instant claims 40 and 48). Interconnected pores or channels are taught at column 1, line 27 (compare instant claims 40, 43, 44, 48, 50, 51, and 56). The scaffold with strands creating pores from 0.2mm (200 microns) to 2mm (2000 microns) is taught at column 4, lines 11-16) (compare instant claims 50-51). Spherical open concavities [pores] of diameter 200 microns to 3000 microns are a particularly suitable substrate which is capable of inducing new bone formation at the site where the material is implanted, is obtained (column 5, lines 5-10) (compare claims 50-51). Thus, with such features, the material exhibits intrinsic osteoinductivity (column 5, lines 5-10). Linear components and curved components are taught in Figure 1 and column 3, lines 1-34, especially lines 33-34 (compare claims 43, 44, and 56). Components that can extend at any angle between 10 degrees and 90 degrees relative to those of an adjacent component are taught at column 3, lines 21-23 (see also column 4, lines 50-54) (compare claims 40, 43, 44, 48, 50, 51, 56, 57, and 58). The pore or channels sizes, mechanical strength of the lattice structure, and directional properties of the lattice structure, can readily be modified or optimized for particular applications (column 5, lines 44-47) (compare claims 40, 43, 44, 48, 50, 51, 56, 60, and 63). An FDM rapid prototyping system is taught at column 4, lines 8-9 (compare instant claims 40 and 48). See also, claims 1-9.
- c. The '478 patent does not teach an extrusion composition comprising polycaprolactone (PCL), but it does teach hydroxyapatite composites including elastomers and polymers. The '478 patent also does not teach specific lay-down patterns of triangles or five-sided polygons.

However, it does teach that the directional properties of the lattice structure can readily be modified or optimized for particular applications (column 5, lines 44-47).

- d. The '680 patent teaches a customized scaffold structure for use in tissue engineering for an individual patient as claimed, including the use of scanning and fused deposition modeling (FDM) (abstract; column 1, lines 16-28; and column 2, lines 11-13) (compare instant claims 40 and 48). FDM employing melt extrusion filaments are taught at column 6, lines 8-12 and 18-22, including FDM operating in X, Y, and Z, axes (column 6, lines 18-22) (compare instant claims 40 and 48). Polymers to be used include polycaprolactone (PCL) (column 8, line 37) and composites including hydroxyapatite (PCL/HA) (column 1, line 52 and 63) (compare instant claims 40 and 48). Example 1 (column 14, lines 30-67 to column 15, lines 1-5) teach a bone regeneration matrix comprising three-dimensional multiple layers that comprise complex architectural features and macroscopic shapes, including linear and curved shapes, which can be manipulated by varying the printing instructions (compare instant claims 40, 43, 44, 48, 50, 51, 56-60, and 62-63). Lines 100 microns wide spaced 300 microns center-to-center along the length of a 2cm axis (each line being 200 microns in depth) is taught at column 14, lines 29-31 (compare instant claims 50 and 51). Polymers such as polycaprolactone (PCL) (column 8, line 37) and composites including hydroxyapatite (PCL/HA) (column 1, line 52 and 63) (compare instant claims 40 and 48). Vertical walls of approximately 60 to 300 microns in diameter are taught as preferred for long-bone fracture repair devices (column 13, line 67 to column 14, lines 1-2) (compare instant claims 60 and 63).
- e. The '872 patent teaches an apparatus for creating three dimensional objects using solid free form fabrication (SFF) or layer manufacturing (column 1, lines 17-20) using X, Y, Z, planes (column 4, lines 21-23) using ceramics (column 11, lines 19 and 59), or polymers (column 11, lines 38-42, and column 12, lines 18-19). The '872 patent teaches that the most popular file format used by all commercial rapid prototyping machines is the .STL format. The .STL format describes a CAD model's surface topology as a single surface represented by triangular facets. By slicing through the CAD model simulated by these triangles, one would obtain coordinate points that define the boundaries of each cross section (column 16 , lines 44-50) (compare instant claims 40, 48, 57, 58, and 62). The ability to form "substantially equal porosities" is taught by the '872 patent at column 17, lines 6-27, which explains in detail how to delineate a boundary of a cross section and interior space may be controlled and

automated, using a computer system wherein the programmed signals provide coordinates for polymer printing in a X, Y, and Z, axis, permitting the user to control the formation of the object of interest (compare instant claims 59 and 62).

- f. The '679 patent provides evidence that the bioceramic hydroxyapatite (such as taught by the '478 patent and the '680 patent) is bioresorbable (see column 7, lines 49-50) (compare instant claims 61and 64).
- g. The level of skill of those in the art encompasses skills in the field of polymer chemistry relating to the construction or generation of tissue scaffold matrices by standard and routine methodologies.
- h. The scope and content of the prior art in the same field of endeavor as that of Applicant's invention, includes a similar and analogous scaffold apparatus and well-known devices for making scaffolds, as evidenced by the '478 patent and the '680 patent.
- i. There were design incentives or market forces which would have prompted the adaptation of the known scaffold apparatus to encompass triangular pores or five-sided polygonal pores, as evidenced by the '872 patent.
- j. The differences between the claimed invention and that of the prior art were encompassed in known variations or in a principle known in the prior art, as evidenced by the '478 patent and the '680 patent.
- k. One of ordinary skill in the art, in view of the design incentives or other market forces, could have implemented the claimed variation of the prior art, and the claimed variation would have been predictable to one of ordinary skill in the art, as evidenced by the '478 patent and the '680 patent.
- l. The prior art contains a base apparatus, device, and known methods of making biocompatible scaffolds, upon which the claimed invention can be seen as an improvement, the improvement being varying lay-down patterns in the scaffold apparatus, as evidenced by the '478 patent and the '680 patent.
- m. The prior art contains a comparable apparatus (scaffold) that was improved upon in the same way as the instant invention, by incorporating PLC and PLC/HA melt extrusion compositions formed with FDM to form scaffolds with various lay-down patterns, as evidenced by the '478 patent and the '680 patent.
- n. One of ordinary skill in the art could have applied the known technique of using PLC and PLC/HA melt extrusion compositions formed with FDM to form scaffolds with various lay-

down patterns, simply by varying the printing instructions on the FDM modeler machine, and the results would have been predictable to one of ordinary skill in the art, as evidenced by the '478 patent, the '680 patent, and the '872 patent.

- o. A person of ordinary skill in the art at the time the invention was made would have reasonably know that a polymer used in biomedical scaffold construction includes polycaprolactone (PCL) and composites including hydroxyapatite (PCL/HA). Further, a person of ordinary skill in the art would have been able to make biomedical scaffold apparatuses using hydroxyapatite and composites comprising hydroxyapatite and polymers, such as polycaprolactone using well-known methodologies and protocols, such as the ones taught by the '478 patent or the '680 patent and the resulting structural composition of the scaffold would have been predictable.
- p. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

In view of the facts recited above, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the prior art elements according to known methods to yield predictable results. The prior art teaches all of the limitations of the claimed invention. In light of the teachings of the '478, '680, and '872 patents, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have varied the lay-down patterns of scaffold apparatus' using PLC and PLC/HA melt extrusion compositions formed with FDM operating in X, Y, Z axes to form scaffolds with various lay-down patterns, simply by varying the FDM printing instructions. The '478 patent teaches a customized three-dimensional, layered, scaffold structure for use in tissue engineering for an individual patient including the aspect of intercrossing filaments stacked in horizontal planes (see abstract; Figures 1 and 2; Examples 1 and 2, columns 3 and 4). Interconnected pores or channels are taught at column 1, line 27. Linear components and curved components are taught in Figure 1 and column 3, line s 1-34, especially lines 33-34. Components that can extend at any angle between 10 degrees and 90 degrees relative to those of an adjacent component are taught at column 3, lines 21-23 (see also column 4, lines 50-54). The '680 patent teaches a customized scaffold structure for use in tissue engineering for an individual patient as claimed, including the use of scanning and fused

deposition modeling (FDM) (abstract; column 1, lines 16-28; and column 2, lines 11-13). Polymers to be used include polycaprolactone (column 8, line 37) and composites including hydroxyapatite and hydroxyapatite (column 1, line 52 and 63). Incorporate of hydroxyapatite crystals into a matrix for bone regeneration are taught at column 9, lines 64-65. Example 1 (column 14, lines 3067 to column 15, lines 1-5) teach a bone regeneration matrix comprising three-dimensional multiple layers that comprise complex architectural features and macroscopic shapes, including linear and curved shapes, which can be manipulated by varying the printing instructions. Further, the '872 patent provides the rationale, teaching, and motivation for using a triangular or modified triangular pore (as polygonal pores) patterns because one of skill in the art would be able to obtain coordinate points and defined boundaries of the scaffold when designing the scaffolds on a CAD system. Moreover, one of skill in the art would be able to create scaffolds with uniform strength and density using the triangular pores or modified triangular pores (as polygonal pores).

The '680 patent teaches the polymer polycaprolactone (PCL) and composites of PCL and hydroxyapatite (HA) used in biomedical scaffold devices. The '478 patent teaches hydroxyapatite in combination with polymers and elastomers. The '679 patent provides evidence that the bioceramic hydroxyapatite is bioresorbable. The specification also teaches this well-known fact at page 41, lines 20-21. The person of ordinary skill in the art could have combined the elements as claimed by known methods to produce a biomedical scaffold comprising PCL or PCL/HA as the bioactive material from which the scaffold was constructed with the requisite shaped pore structures, as set forth above. One of skill in the art would have recognized that the results of the combination of PCL, as the polymer, and HA would have yielded nothing more than predictable results to one of ordinary skill in the art at the time the invention was made.

Design incentives to vary the pattern include variance in the purpose or anatomical placement of the scaffold (for example, differences in mechanical load strength and suture pull-out strength of the scaffold would vary depending on whether the scaffold was placed in or near a weight bearing anatomical part or subjected to intense mechanical stresses), improvements in offset yield strength, or improvements in porosity that could affect blood flow or cellular influx into the scaffold. Market forces would have also prompted the need for variations due to the lack of availability of scaffolds for an increasing variety of anatomical structures and competition in the market for product designed to meet specific anatomical and mechanical repair needs. These design incentives and market forces are also evidenced by the '478 patent, the '680 patent, and the '872 patent (see i.e. the '680 patent, column 1, lines 20-28). The composition (i.e. PLC and PLC/HA) of the claimed scaffold is old and well known in the art, as

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demonstrated by the '680 patent. The only difference between the instant invention and the prior art is the lay-down pattern of the melt extrusion filament used to construct the scaffold apparatus. However, the '478, '680, and '872 patents clearly teach that this pattern can be varied, depending on the design and structural needs of the maker. Thus, the variations in pattern lay-down are known variations of the prior art and they would have been predictable to one of skill in the art at the time the invention was made.

Moreover, “[i]t is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.” In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held *prima facie* obvious).

Regarding Applicant's remarks against the previously cited art of record, the '478 patent and the '680 patent, Applicant incorporates the arguments applied against the '680 alone, to wit, Applicant argues that although it has been suggested that different lay-down patterns can be manipulated by varying the printing instructions, there is a lack of suggestion of a lay down pattern forming triangular or five-sided polygon pores in Cima and this would create an undue burden of experimentation (Remarks, p. 11, second paragraph). Applicant argues that the advantages conferred and unexpected results obtained by a lay-down pattern which forms triangular and five sided polygonal pores would not have been obvious to a person of ordinary skill in the art since there is no suggestion in Cima on how such advantages can be achieved (Remarks, p. 11, last paragraph). Applicant also argues that the teachings of Cima prefer a 3DP method over other solid free-form [sic] methods, such as FDM (Remarks, p. 11, last paragraph). Applicant further argues that there is no evidence of design incentives or other market forces has been presented to show that one of ordinary skill in the art would have been motivated to arrive at the claimed lay-down pattern (Remarks, p. 12, last paragraph). Applicant also argues that it would not have been obvious to a person of ordinary skill in the art to provide the advantages and unexpected results as described in the specification at page 41, line 9 to page 42, line 13 (Remarks, p. 13, first paragraph). Applicant argues that “it is known that almost all inventions, patentable or not, are founded upon market

forces or design incentives" (Remarks, p. 13, second paragraph). Applicant argues that this test is "inappropriate" and that "the test should be whether the invention is novel, useful, and unobvious (Remarks, p. 13, second paragraph). Applicant argues that there is no motivation for the person of ordinary skill in the art to arrive at the lay-down pattern as recited in claims 40 and 48 because of a lack of an express suggestion in either Richter and Cima (Remarks, p. 13, third paragraph). Applicant's arguments have been fully considered, but they are not persuasive.

Regarding Applicant's argument drawn to a burden of undue experimentation over selecting a triangular or modified triangular (i.e. polygonal) pore structure, the '872 patent provides the requisite teachings and motivation for using this pattern (see above).

Applicant argues that the instant apparatus has unexpected advantages over the prior art and refers to pages 41, line 9, to page 42, line 13 of the specification to elucidate those advantages. According to the specification, the scaffold designs allow for the flow transport of nutrients and wastes, have the capacity to deliver a high volume of cells, have chemical and physical properties that allow load-bearing applications, as well as active tissue integration of bone and cartilage tissue components and vascularization to enhance nutrient transport (p. 41, lines 9-16). The scaffold degradation and resorption kinetics are from 6-12 months and the incorporation of the bioresorbable ceramic (i.e. hydroxyapatite, p. 41, line 21) produces a hybrid material that supports triggering the desired degradation and resorption kinetics (p. 41, lines 17-21 to p. 42, lines 1-3). Advantages of using a composite HA/TCP material are discussed at page 42, lines 4-13. Applicant's arguments that these are unique and previously unknown advantages of tissue scaffolds is without merit, as these "advantages" are taught and well known in the art of record. For example, the '478 patent teaches the advantages of bone implants at column 1, lines 18-27, including osteoconductivity, osteointegration, secure incorporation, the lattice structure permitting bone growth into the porous spaces. The benefits of a composite material, including a material comprising hydroxyapatite are taught at column 5, lines 11-35. The '680 patent teaches the advantages of scaffolds in tissue generation that can be customized for the particular need (column 2, lines 3-13). Bioerodible and composite materials are taught that provide a suitable environment for cell transplantation, matrix-guided tissue regeneration, and tissue in-growth (column 2, lines 16-26). The '680 patent also teaches that devices for tissue regeneration can be constructed to fit the individual patient, individual cell type, or organ structure (column 3, lines 1-14 and column 13, lines 1-13). The device can include bioactive agents and can be structured to deliver drugs to the site of regeneration (column 3, lines 1-14). In the case of bone ingrowth, channels that permit the growth of new blood vessels from adjoining bone and periosteal tissue are taught at column 13, lines 9-13.

Applicant's argument that the teachings of the '680 patent "prefer a 3DP method over other solid free-form [sic] methods, such as FDM" is spurious. As stated of record and set forth above, the '680 patent teaches solid free form methods including FDM. Whether prior art teaches one technique as preferred over another for a particular application does not otherwise negate the teaching of the other embodiment.

Regarding Applicant's argument that the market forces or design incentives test is "inappropriate" Applicant is directed to KSR International v. Teleflex, Inc. 550 US ___, 1275 S. Ct 1727, 82 USPQ2d 1385 (April 30, 2007) and to the Examination Guidelines for Determining Obviousness under 35 USC 103(a) in view of the Supreme Court Decision in KSR International v. Teleflex, Inc., specifically at Rationale F (published in the Federal Register, Vol 72, No. 195, Wednesday, 10 October 2007, pages 57526-57535, especially at page 57533). Insofar as Applicant's representative articulates his "opinion" on what the "test" should be, Applicant is referred to both the Supreme Court opinion in KSR v. Teleflex and the aforementioned USPTO Examination Guidelines.

With regard to Applicant's arguments regarding the strict construction and application of the TSM test, Applicant is directed to KSR v. Teleflex, Inc., 550 US at ___, 82 USPQ2d 1385 (30 April 2007), which states, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." (KSR, at 1396). The Court continued, stating that "helpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents. The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents." KSR, at 1390. As such, the rejection at issue and its analysis under 103(a) meets all of the *prima facie* requirements under Graham v. Deere (1966) (*supra*) and KSR v. Teleflex (2007) (*supra*).

Further, the rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992); and MPEP 2144. See also *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000)(setting forth test for implicit

teachings); *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings).

It is also noted that the intended use of the claimed apparatus “in tissue engineering” (see, i.e. preamble of claims 40 and 48) is not relevant where the statement of intended use does not distinguish over the prior art composition. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963) (The claims were directed to a core member for hair curlers and a process of making a core member for hair curlers. Court held that the intended use of hair curling was of no significance to the structure and process of making.); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim did not distinguish over the prior art apparatus). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (anticipation rejection affirmed based on Board’s factual finding that the reference dispenser (a spout disclosed as useful for purposes such as dispensing oil from an oil can) would be capable of dispensing popcorn in the manner set forth in appellant’s claim 1 (a dispensing top for dispensing popcorn in a specified manner)) and cases cited therein. See also MPEP § 2112 - § 2112.02.

New Claim Rejections/Objections

Claim Rejections - 35 USC § 112, Second Paragraph

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 59 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “substantially equal porosities” is not limited in terms of its metes and bounds. There is no porosity reference in the claims by which one could measure against a standard of equal porosities.

Claim Objections

15. Claim 40 is objected to because of the following informalities: the word “layers” in claim 40, line 11 is misspelled as “layet5”. Appropriate correction is required.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Examiner, Art Unit 1647